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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,033	11/21/2001	Stephen J. Chudzik	9896.129.3.1.1	9835

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,033

Applicant(s)

CHUDZIK ET AL.

Examiner

Jennifer K. Michener

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-40 and 51-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-40 and 51-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/24&26/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Examiner acknowledges and appreciates Applicant's cancellation of non-elected claims. Claims 31-40 and 51-78 are pending.

Information Disclosure Statement

2. The information disclosure statement filed 3/26/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but only the documents which have been provided have been considered. The documents through which examiner has crossed, were not provided by Applicant and were therefore not yet considered by Examiner. Examiner kindly requests Applicant submit the non-considered documents.

Claim Rejections - 35 USC § 112

3. The rejection of claims 31-40 under 35 U.S.C. 112, second paragraph, has been withdrawn based on Applicant's amendments.

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Based on Applicant's amendments, the following objection is made:

Claim Objections

4. Claim 1 is objected to because of the following informalities: in amending the claim, the phrase —the composition—was added just prior to “the method”. This does not flow correctly, gramatically.

Appropriate correction is required.

Additionally, Examiner notes that all of the added limitations have been merely added to the preamble as opposed to the body of the claim, as suggested by Examiner. While the phrase “the composition” in the body of the claim refers to the specifics of the composition now in the preamble and is given weight by Examiner, the elements of the preamble requiring release of the bioactive agent are merely intended use of the product.

Claim Rejections - 35 USC § 102

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 31-34, 36, 38, 51-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitbourne et al. (6,110,483).

Examiner maintains the rejection of claims 31-34, 36, and 38.

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Claims 51-52 are added to the rejection, as necessitated by the addition of these new claims. Whitbourne teaches coating a stent or catheter made from metal or polymers (col. 2, lines 25-34).

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 35, 37, 39-40, and 53-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al.

Examiner maintains the rejections of claims 35, 37, and 39-40.

Claims 53-58, 61-62, 67-69, and 71-78 are added to this rejection, outlined below, as necessitated by the addition of these new claims.

Claims 59-60, 63-66, 70 are added to this rejection for the same reasons outlined regarding claims 34-37 in the previous office action.

Regarding claims 53-58 and 71-78, Whitbourne teaches the treatment of catheters or stents, but fails to teach that the catheters may be urinary or intravenous catheters or that the stents may be self-expanding or balloon-expandable. However, it is Examiner's position that selection of urinary or intravenous catheters from the broad class of "catheters" or self-expanding versus balloon-expandable stents from the broad class of "stents" taught by Whitbourne would have been immediately obvious to one of ordinary

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skill in the art. Catheters are frequently used in the urinary tract or intravenously and stents are made to expand once positioned within a vessel through the use of either shape-memory material (self-expandable) or balloons. Whitbourne teaches stainless steel, silicone and other metals and polymers for the making of such devices (col. 2, lines 25-30). Whitbourne teaches that the bioactive agent may be an antimicrobial agent (silver or gentamicin) (paragraphs bridging col.s 8-9).

The polymer composition inherently affects the release of the bioactive agents from the device, as required by claim 61.

Regarding claim 62, the polybutylmethacrylate of Whitbourne, taught in the previous office action, is the claimed polyalkylmethacrylate with a chain length of 4 carbons.

Regarding claims 67-68, Whitbourne teaches the use of solvents to dissolve all constituents. The bioactive agent composition was addressed in the 102 rejection of claim 38 in the previous office action.

Regarding newly-added claim 69, Whitbourne teaches anti-cancer agents, among others (col. 9, line 4).

Response to Arguments

9. Applicant's arguments filed 4/12/2004 have been fully considered but they are not persuasive.

Applicant argues that the reference fails entirely to teach or suggest the use of polyalkylmethacrylate of the type claimed.

Examiner disagrees.

Whitbourne teaches a polymeric butylmethacrylate (col. 2, line 21). The "butyl" of Whitbourne is the "alkyl" group claimed by Applicant. In at least claim 35, Applicant requires the polyalkylmethacrylate to be poly-n-butylmethacrylate, as taught by Whitbourne, meeting the limitation of the dependent claim and therefore, inherently, the independent claim. Differences in nomenclature do not change the identity of the chemical.

Regarding the argument that the polymeric butylmethacrylate of Whitbourne is merely used as an example of the types of polymers allowed by Whitbourne, Examiner notes that the classification of such a compound as a certain type of chemical does not alter the fact that Whitbourne teaches the same polymer as Applicant. The form and function of the same chemicals will be the same.

Applicant argues that the reference only teaches ethylene vinyl acetate copolymer, similar to what is known in the general body of art, not Applicant's second claimed polymer.

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Examiner maintains that Whitbourne's ethylene vinyl acetate co-polymer is the same as Applicant's "poly(ethylene-co-vinyl acetate)". The slight change in nomenclature does not render the chemical different.

Applicant argues that Whitbourne requires crosslinking, whereas Applicant does not. Examiner notes that the claims do not preclude crosslinking. Additionally, Whitbourne teaches that his coatings may be "made without crosslinking".

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lentz 2002/0133183 teaches coating stents with the polymers of Applicant. Falotico (WO 01/87263 A2), cited by Applicant in the submitted IDS, teaches coating a medical device with a bioactive agent in a polymeric matrix of polybutylmethacrylate and ethylene-co-vinylacetate (p. 24, line 30).

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

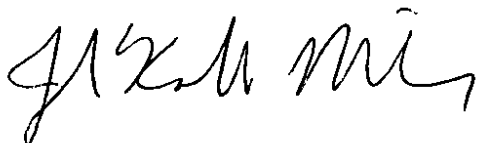
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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Patent Examiner
Technology Center 1700
June 3, 2004